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EXAMINER

LAM.A

ART UNIT

PAPER NUMBER

3763

DATE MAILED:

09/12/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

**Office Action Summary**

Application No.

09/430,050

Applicant(s)

CHU ET AL.

Examiner

Ann Y. Lam

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 10, 16 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) 10, 16-20, 22 and 23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9, 11-15 and 21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

1. Claims 1-6, 12, 13, 15 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Lee, 5125,904. Lee discloses a valve body (14) having a lumen therethrough; means (34) for breaking said valve body along a predetermined location; means (16b) for coupling said valve body to a peel-away sheath for coupling said peel-away sheath lumen to said valve body lumen; means (valve body lumen) for receiving a compressible valve sleeve having a lumen therethrough for coupling said valve sleeve lumen to said valve body lumen; and means (22) for compressing said valve sleeve for restricting any fluid flow from said peel-away sheath lumen through ~~valve and valve~~ sleeve lumen.

As to claim 2, the valve sleeve inherently includes a free end extending past said means for compressing, and further comprising means (proximal end of 24) for receiving a catheter tip within said valve sleeve lumen free end while said means for compressing is compressing said valve sleeve, such that said valve sleeve lumen is substantially occluded by said inserted catheter tip while said catheter tip is inserted.

As to claim 3, Lee discloses a means (22 and 24) for reversibly restricting fluid flow from said sheath lumen coupled to said sheath proximal end; means (34) for breaking apart said fluid flow restricting means responsive to applied force; and means (proximal end of 24) for admitting a catheter distal end into said valve.

As to claim 4, the means (22 and 24) for reversibly restricting flow has an open position for allowing flow therethrough and a closed position for substantially restricting flow, wherein said means (proximal end of 24) for admitting said catheter distal end includes means for admitting said catheter distal end while said means for restricting flow is in said closed position, see column 5, lines 62-66.

As to claim 5, said means (22 and 24) for restricting flow includes a flexible, constrictable tube (24) having a lumen therethrough.

As to claim 6, said means (22 and 24) for restricting flow includes means for pinching (22) said flexible tube for constricting said flexible tube lumen.

As to claim 12, Lee discloses a tubular, distal introducer sheath (12) having a proximal region and a lumen therethrough, said sheath having at least one longitudinal strip (34) for preferentially tearing said sheath along said strip; a tubular, flexible, proximal valve sleeve (24) having a proximal region, a distal region, and a lumen therethrough; and a valve body (16) having a lumen therethrough and being sealingly coupled to said introducer sheath proximal region, said valve having at least one weakened region (34) for preferentially splitting said valve into at least two pieces responsive to an applied breaking force, said valve body having a seat (proximal end of 16) for mating to said proximal valve sleeve distal region, see Figure 2, said valve body

including a pinch member (22) for pinching said flexible valve sleeve and having a closed position for constricting fluid flow through said valve sleeve and an open position for admitting a catheter inserted through said valve sleeve, see column 5, lines 62-66.

As to claim 13, said flexible valve sleeve includes a free portion proximal of said pinch member for admitting said catheter into said sleeve free portion while said pinch member is in said closed position, see Figure 2.

As to claim 15, Lee discloses a breakaway distal portion (34) having a lumen therethrough for receiving said introducer sheath proximal region; and a proximal portion (16) including two opposed valve body members, at least one of which is movable relative to the other and having concave surfaces therebetween for receiving a flexible valve sleeve therebetween, said valve body opposed members having an open position and a closed position, wherein said valve body members move apart relative to each other to reach said open position and said valve body opposed members move together relative to each other to reach said closed position, see column 5, lines 62-66, and column 6, lines 9-10, wherein said flexible sleeve has a lumen therethrough and said sleeve and sleeve lumen are constricted between said body members in said closed position, such that fluid flow through said sleeve is substantially restricted in said closed position, see column 5, lines 1-2.

As to claim 21, said valve body members (16) are considered pivotally mounted to each other along at least one hinge oriented substantially parallel to said valve body lumen longitudinal axis. (The valve body members (16) are integral with the hinge.)

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2. Claims 1-9, 11-15 and 21 are rejected under 35 U.S.C. 102(e) as being anticipated by Heck, 6,083,207. Heck discloses means (212) for breaking said valve body along a predetermined location; means (70, 71) for coupling said valve body to a peel-away sheath for coupling said peel-away sheath lumen to said valve body lumen; means (50) for receiving a compressible valve sleeve having a lumen therethrough for coupling said valve sleeve lumen to said valve body lumen; <sup>(could add 56)</sup> and means (52) for compressing said valve sleeve for restricting any fluid flow from said peel-away sheath lumen through valve and valve sleeve lumen.

As to claim 2, the valve sleeve inherently includes a free end extending past said means for compressing, and further comprising means (206) for receiving a catheter tip within said valve sleeve lumen free end while said means for compressing is compressing said valve sleeve, such that said valve sleeve lumen is substantially occluded by said inserted catheter tip while said catheter tip is inserted.

As to claim 3, <sup>Heck</sup> Lee discloses a means <sup>856</sup> (52, 20) for reversibly restricting fluid flow from said sheath lumen coupled to said sheath proximal end; means (70, 71) for breaking apart said fluid flow restricting means responsive to applied force; and means (50) for admitting a catheter distal end into said valve.

As to claim 4, the means <sup>856</sup> (52, 20) for reversibly restricting flow has an open position for allowing flow therethrough and a closed position for substantially restricting flow, wherein said means (50) for admitting said catheter distal end includes means for admitting said catheter distal end while said means for restricting flow is in said closed position,.

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As to claim 5, said means <sup>+ 56</sup> (52, 20) for restricting flow includes a flexible, constrictable tube (20) having a lumen therethrough.


As to claim 6, said means <sup>+ 56</sup> (52, 20) for restricting flow includes means (52) for pinching said flexible tube for constricting said flexible tube lumen.

As to claim 7, said means for pinching has at least two portions (26, 28) movable <sup>+ 56</sup> with respect to each other, said two portions having means (52) for accepting and pinching said flexible tube therebetween, said two portions together having an open position and a closed position.

As to claim 8, said movable pinching member portions are hingedly coupled together with at least one hinge, see column 7, lines 33-36, and see Figure 3.

As to claim 9, said sheath has a longitudinal axis and said at least one hinge has an axis substantially parallel with said sheath longitudinal axis and said hinge enables movement of said pinching member portions about said hinge longitudinal axis for pinching said flexible tube in said closed position, see column 7, lines 33-36, and see Figure 3.

As to claim 11, when in said closed position, said pinching members <sup>+ 56</sup> (52) include means for leaving sufficient space in said flexible tube lumen for passage of a guide wire.

As to claim 12,  Heck discloses a tubular, distal introducer sheath (20) having a proximal region and a lumen therethrough, said sheath having at least one longitudinal strip (212) for preferentially tearing said sheath along said strip, see column 9, lines 7-9; a tubular, flexible, proximal valve sleeve (medical device, see column 9, lines 18-19)

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having a proximal region, a distal region, and a lumen therethrough; and a valve body (12) having a lumen therethrough and being sealingly coupled to said introducer sheath proximal region, said valve having at least one weakened region (near 94) for preferentially splitting said valve into at least two pieces responsive to an applied breaking force, said valve body having a seat (50) for mating to said proximal valve sleeve distal region, said valve body including a pinch member <sup>56</sup>(52) for pinching said flexible valve sleeve and having a closed position for constricting fluid flow through said valve sleeve and an open position for admitting a catheter inserted through said valve sleeve.

As to claim 13, said flexible valve sleeve includes a free portion proximal of said pinch member for admitting said catheter into said sleeve free portion while said pinch member is in said closed position.

As to claim 14, said valve body pinch member (52) includes a recess therein for allowing passage of a guide wire through said pinch member while said pinch member is in said closed position.

As to claim 15, <sup>Lee</sup>Lee discloses a breakaway distal portion (20) having a lumen therethrough for receiving said introducer sheath proximal region; and a proximal portion (12) including two opposed valve body members (26, 28), at least one of which is movable relative to the other and having concave surfaces therebetween for receiving a flexible valve sleeve therebetween, said valve body opposed members having an open position and a closed position, wherein said valve body members move apart relative to each other to reach said open position and said valve body opposed



members move together relative to each other to reach said closed position, see column 7, lines 33-37, and column 8, lines 26-30) wherein said flexible sleeve has a lumen therethrough and said sleeve and sleeve lumen are constricted between said body members in said closed position, such that fluid flow through said sleeve is substantially restricted in said closed position.

As to claim 21, said valve body members (26, 28) are considered pivotally mounted to each other along at least one hinge oriented substantially parallel to said valve body lumen longitudinal axis, see column 7, lines 33-37, and column 8, lines 26-30.

### ***Response to Arguments***

Applicant traverses Examiner's assertion in the Restriction requirement that currently no claim is generic. Applicant argues that at least independent claims 1, 3, 12 and 15, along with dependent claims 2, 4-7, 11, 13-14 and 17-20 recite elements that are common to all asserted patentably distinct species of the claimed invention, see page 1, lines 8-9, and page 2, lines 1-2, of Applicant's response.

In response, Examiner partly agrees with Applicant. Examiner hereby withdraws the assertion that currently no claim is generic. However, Examiner asserts, contrary to Applicant, that independent claims 1, 3, 12 and 15, along with independent claims 2, 4-7, 13 and 17-19 recite elements that are common to all asserted patentably distinct species, and thus are generic claims. However, Claims 11, 14 and 20 recite a means for leaving sufficient space, or specifically a recess, in the flexible tube lumen for

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passage of a guide wire; however, this means is not disclosed in the patentably distinct species disclosed in Figure 4. Claim 15 recites that the valve body members have concave surfaces, see lines 5-6 of Claim 15; however, this means is not disclosed in the patentably distinct species disclosed in Figure 4.


### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Y. Lam whose telephone number is (703) 306-5560. The examiner can normally be reached on T-F 8-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Richard Seidel can be reached on (703)308-5115. The fax phone numbers for the organization where this application or proceeding is assigned are (703)305-3590 for regular communications and (703)306-4520 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0858.

A.L.   
September 6, 2001

  
ANH TUAN T. NGUYEN  
PRIMARY EXAMINER  
